INTHE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

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ANNIE TUMMINO, in her individual capacity, as Vice-Chair of the New York State Reproductive Rights Task Force, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; ERIN T. MAHONEY, in her individual capacity, as Chair of the New York State Reproductive Rights Task Force, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; CAROL GIARDINA, in her individual capacity, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; KELLY MANGAN, in her individual capacity, as President of the University of Florida Campus Chapter of the National Organization for Women, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; STEPHANIE SEGUIN, in her individual capacity, as Chair of the Florida National Organization for Women Young Feminist Task Force, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; LORI TINNEY, in her individual capacity, as President of the Gainesville Chapter of the National Organization for Women, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; JENNIFER BROWN, in her individual capacity, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; CANDACE CHURCHILL, in her individual capacity, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; and FRANCIE HUNT, in her individual capacity, as Coordinator of the Morning-After Pill Conspiracy, and on behalf of women who need Emergency Contraception; ASSOCIATION OF REPRODUCTIVE HEALTH PROFESSIONALS, on its own behalf and on behalf of its members and women who need Emergency Contraception; and NATIONAL LATINA INSTITUTE FOR REPRODUCTIVE HEALTH, on its own behalf and on behalf of women who need Emergency Contraception,

Plaintiffs,

CV-05-0366 (ERK/VVP)

v.

ANDREW C. VON ESCHENBACH, in his official capacity as acting commissioner of the Food and Drug Administration,

Defendant.

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THIRD AMENDED COMPLAINT

Plaintiffs, by and through their undersigned attorneys, bring this complaint against the defendant, his agents and successors in office, and in support thereof aver the following:

1. This is a challenge under the Administrative Procedures Act (APA) and the United States Constitution to the denial by the Food and Drug Administration (FDA) of a Supplemental New Drug Application (SNDA) and a citizen's petition ("citizen's petition") seeking to switch the emergency contraception ("EC") drug Plan B from prescription-only availability to over-the-counter status ("OTC switch"). Plaintiffs claim that this denial violates the rights of women who need EC to privacy and equal protection under the Fifth Amendment, and that the denial violates their rights and the rights of women who need EC because it exceeds the statutory authority of the FDA and is arbitrary and capricious. Plaintiffs seek injunctive relief requiring the defendant to approve the OTC switch, or such other equitable relief as the Court may deem appropriate, and a declaratory judgment that the FDA's denial violates the APA and violates the constitutional rights of women who need EC.

I. Jurisdiction and Venue

2. This Court has jurisdiction under 28 U.S.C. § 1331 because this case arises under the Constitution and laws of the United States.

3. Venue is proper in this district under 28 U.S.C. § 1391(d) because one of the plaintiffs resides in this district and the defendant is an officer of the United States acting in his official capacity.

II. The Parties

A. Plaintiffs

4. Plaintiff Annie Tummino is a resident of Brooklyn, New York. She sues on her own behalf, as Vice-Chair of the New York State Reproductive Rights Task Force and as Coordinator of the Morning-After Pill Conspiracy ("MAP Conspiracy"), and on behalf of women who need EC.

5. Plaintiff Erin T. Mahoney is a resident of New York, New York. She sues on her own behalf, as Chair of the New York State Reproductive Rights Task Force and as Coordinator of the MAP Conspiracy, and on behalf of women who need EC.

6. Plaintiff Carol Giardina is a resident of New York, New York. She sues on her own behalf, as Coordinator of the MAP Conspiracy, and on behalf of women who need EC.

7. Plaintiff Kelly Mangan is a resident of Gainesville, Florida. She sues on her own behalf, as President of the University of Florida Campus Chapter of the National Organization for Women, as Coordinator of the MAP Conspiracy, and on behalf of women who need EC.

8. Plaintiff Stephanie Seguin is a resident of Gainesville, Florida. She sues on her own behalf, as Chair of the Florida National Organization for Women Young Feminist Task Force and as Coordinator of the MAP Conspiracy, and on behalf of women who need EC.

9. Plaintiff Lori Tinney is a resident of Gainesville, Florida. She sues on her own behalf, as President of the Gainesville Chapter of the National Organization for Women, Gainesville, FL and as Coordinator of the MAP Conspiracy, and on behalf of women who need EC.

10. Plaintiff Jennifer Brown is a resident of Gainesville, Florida. She sues on her own behalf, as Coordinator of the MAP Conspiracy, and on behalf of women who need EC.

11. Plaintiff Candace Churchill is a resident of Gainesville, Florida. She sues on her own behalf, as Coordinator of the MAP Conspiracy, and on behalf of women who need EC.

12. Plaintiff Francie Hunt is a resident of Nashville, Tennessee. She sues on her own behalf, as Coordinator of the MAP Conspiracy, and on behalf of women who need EC.

13. The MAP Conspiracy is a coalition of feminist organizations leading the grassroots movement to make the Morning-After Pill an over-the-counter drug by raising public consciousness about the ways that women have to conspire to obtain it. Since February 2004, the MAP Conspiracy has organized speak-outs where women publicly testify from their own experience about their need for the Morning-After Pill and the obstacles they face obtaining it. Members of the MAP Conspiracy also testified at the December 2003 FDA public hearings on the Barr application for approval of over-the-counter status for Plan B.

14. Each of the individual plaintiffs listed in paragraphs 4-12 above has access to one or more doses of Plan B, and each of them intends, plans, and has pledged to provide Plan B to friends or other women of any age whom they learn need Plan B to prevent pregnancy. None of the individual plaintiffs listed in paragraphs 4-12 above is licensed or authorized by law in any state to prescribe or dispense drugs. Consequently, unless the OTC switch for Plan B is approved, each of the individual plaintiffs listed in paragraphs 4-12 above risks violating federal

and state criminal statutes if she carries through on her plan to provide Plan B to women who need it to prevent pregnancy. *See*, *e.g.*, 21 U.S.C. §§ 353(b)(1), 333(a), 333(b) (2005); § 465.015, Fla. Stat. (2004).

15. Plaintiff Association of Reproductive Health Professionals (ARHP) is a non-profit membership association composed of experts in reproductive health. These professionals include physicians, advanced practice clinicians (nurse practitioners, nurse midwives, physician assistants), researchers, educators, pharmacists, and other professionals in reproductive health, some of whom have authority to prescribe drugs and some of whom do not. ARHP and its members provide reproductive health services and education, conduct reproductive health research, and influence reproductive health policy. Specifically, ARHP works to improve the reproductive health of women by reducing the number of unintended pregnancies among women. ARHP, along with Princeton University's Office of Population Research (OPR), manages the *Emergency Contraception Hotline* (1-888-Not-2-Late) and *Website* (www.not-2-late.com), which aim to prevent unintended pregnancy by providing women and their partners information about, and rapid access to, emergency contraception. Both the *Hotline* and *Website* are highly utilized tools, currently receiving an average of 60,000 calls and 500,000 website visits per year. The *Hotline* is an automated, toll-free, 24-hour, confidential service available in both English and Spanish that gives callers general emergency contraception information and a list of the five emergency contraception providers nearest to them (including a list of pharmacists in states where pharmacists are permitted by state law to dispense EC). It is available from any phone in the United States, Puerto Rico, U.S. Virgin Islands, British Columbia, and the Yukon Territory. The *Website*, available in English, French, Spanish, and now Arabic, is the most comprehensive emergency contraception clearinghouse in the world available to anyone via the

World Wide Web. It features frequently asked questions about emergency contraception, a publications bibliography, an EC materials database, and a searchable database of EC providers across the country, Puerto Rico, Guam, U.S. Virgin Islands, and British Columbia. The full directory of providers can be searched by city, state, area code, and zip code. The NOT-2-LATE database also lists pharmacists in Alaska, California, Washington State, New Mexico, and British Columbia. ARHP and OPR work closely with local pharmaceutical associations to sign up pharmacists who dispense EC behind the counter. Hawaii has recently become the fifth state—joining Alaska, California, New Mexico and Washington—to allow direct dispensation of EC by pharmacists. ARHP is working closely with pharmacy organizations and state officials in Hawaii to list pharmacists once they are trained. ARHP has petitioned the FDA to switch EC to OTC status. The prescription requirement for Plan B interferes with ARHP's ability to educate health care providers and the public about emergency contraception, interferes with ARHP's efforts to reduce the number of unintended pregnancies and its efforts to use the *Emergency Contraception Hotline* and *Website* to achieve that goal, and interferes with its members' ability to accomplish the goal of improving the reproductive health of women. ARHP sues on its own behalf, on behalf of its members who lack prescribing authority and their patients and clients who seek emergency contraception, and on behalf of the women who utilize the Hotline and Website to obtain access to EC.

16. Plaintiff National Latina Institute for Reproductive Health (NLIRH) is a non-profit organization formed under section 501(c)(3) of the Internal Revenue Code. NLIRH conducts an EC education and outreach project which seeks to educate providers of EC and potential users of EC about what EC is, how to use it, and how to obtain it and, for providers, how to incorporate it into their practice. NLIRH has conducted such an education and outreach project in the Bronx,

and plans additional such projects at several locations in Brooklyn and the Bronx through June of 2005. NLIRH's EC education outreach projects are impeded by the prescription requirement for EC. If EC is switched to OTC, NLIRH will be able to improve access to EC by enhancing its EC educational programs for both the health care providers and the public participants involved in those projects. NLIRH sues on its own behalf and on behalf of the women participants in its EC projects who are of childbearing age.

B. Defendant

17. Andrew C. von Eschenbach is the acting commissioner of the FDA. Von Eschenbach is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. He is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health. He is sued in his official capacity.

III. Statutory and Regulatory Background

18. Under FDA regulations, "[a]ny drug limited to prescription use . . . shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and he finds that the drug is safe and effective for use in self-medication as directed in proposed labeling." 21 C.F.R. § 310.200(b) (2005); *see also* 21 U.S.C. § 353(b)(3) (2005) ("The Secretary may by regulation remove drugs subject to sections 352(d) and 355 of this title from

the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.").

19. An approved drug is suitable for OTC use when: (1) the drug is safe for self-medication, 21 C.F.R. § 310.200(b); 21 C.F.R. § 330.10(a)(4)(i); (2) the drug is effective when self-administered, 21 C.F.R. § 310.200(b); 21 C.F.R. § 330.10(a)(4)(ii); (3) the condition to be treated is self-diagnosable; and (4) the drug's labeling is tailored to self-administration, 21 C.F.R. § 310.200(b); 21 C.F.R. § 330.10(a)(4)(v).

20. By statute, the manufacturer of a prescription drug may file a supplemental new drug application with the FDA seeking to switch the drug to OTC status. 21 U.S.C. § 355(b). Such an application must be acted upon by the FDA within 180 days of its filing. 21 U.S.C. § 355(c).

21. In addition, FDA regulations explicitly authorize the use of a citizen's petition to seek a switch from prescription to OTC status: "A proposal to exempt a drug from the prescription-dispensing requirements of section 503(b)(1)(C) of the act may be initiated by . . . any interested person . . . fil[ing] a petition . . . pursuant to Part 10 of this chapter . . . ." 21 C.F.R. § 310.200(b). Once a citizen's petition has been filed, the FDA is required by its regulations to either approve the petition, deny the petition, or "[p]rovide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information." 21 C.F.R. § 10.30(e)(2).

22. During the process of considering an application for an OTC switch, the FDA typically receives the advice of the FDA's OTC advisory committee meeting together with the FDA's advisory committee that has specific expertise in the product under consideration. In the case of Plan B, the latter committee is the Advisory Committee for Reproductive Health Drugs. These advisory committees are authorized by, *inter alia*, 21 U.S.C. § 355(n) (2005).

23. Dispensing a prescription drug other than by prescription is an act of "misbranding" under federal law. 21 U.S.C. § 353(b)(1). Introducing a misbranded drug into interstate commerce is a "prohibited act," 21 U.S.C. § 331(a), punishable by not more than one year imprisonment or a fine of up to $1000 or both. 21 U.S.C. § 333(a)(1).

IV. Factual Allegations

A. Making Plan B Available OTC to Women of All Ages Would Improve the Public Health and Enable Women to Reduce their Risk of Unplanned Pregnancies.

24. Unintended pregnancy is a significant public health problem in the United States. The United States has one of the highest rates of unintended pregnancy compared to other developed countries. The rate of teen pregnancy in the United States is also one of the highest among developed countries. Wider access to EC will reduce unintended pregnancies, including among teenagers.

25. The risks of pregnancy and childbirth, including maternal death, can be serious and exceed the risks associated with EC.

26. Plan B is a drug used only by women, and every woman of childbearing age is a potential user of Plan B.

27. Plan B (Levonorgestrel) is an emergency contraceptive drug in tablet form that can be used to prevent pregnancy following an act of intercourse in which no contraceptive was used or the contraceptive method used failed.

28. When taken within 72 hours of unprotected intercourse, Plan B reduces the risk of pregnancy by approximately 89 percent after a single act of unprotected sex. As the interval between intercourse and the start of treatment increases, Plan B's effectiveness declines, and the risk of pregnancy increases. Plan B does not interfere with an established pregnancy.

29. Switching Plan B to OTC status will promote public health because Plan B is only effective for a short time after unprotected sex, and it works most effectively if used within twenty-four hours of unprotected sex. Because contacting a physician and obtaining and filling a prescription hinder women from obtaining Plan B in a timely fashion, making Plan B available OTC will allow more women to use the treatment, and enable more women to prevent unwanted pregnancies, to the benefit of public health.

30. Limiting Plan B to prescription use is not necessary for the protection of public health.

31. Plan B is safe for self-medication because it is not toxic to the woman (or to the embryo or fetus if a pregnancy had been previously established in the woman).

32. Plan B has a low risk of abuse or overdose, and if overdose occurs is unlikely to lead to serious consequences.

33. Plan B's side effects are well-known and minor.

34. Plan B is effective when self-administered. Its administration is simple and relies only on assessments as to time elapsed since sexual intercourse that can be independently made by the woman, and any interaction between Plan B and other drugs would be nonfatal and unlikely to seriously affect Plan B's efficacy.

35. The condition Plan B treats — contraceptive failure or failure to use contraception during intercourse — is one that is readily diagnosable by a woman.

36. Plan B has no contraindications that would pose a danger to the patient.

37. The existing patient labeling for Plan B is tailored to self-administration in that it is simple, clear, comprehensive and easy to follow.

38. Both the American Medical Association and the American College of Obstetricians and Gynecologists support switching Plan B to OTC status. *See* Dec. 5, 2000 Statement of American Medical Association; December 13, 2001 Statement of the American College of Obstetricians & Gynecologists.

B. Public Health Organizations Filed Two Citizen's Petitions with the FDA Seeking to Increase Access to Emergency Contraception.

39. On November 23, 1994, the Center for Reproductive Law and Policy (now the Center for Reproductive Rights) submitted a Citizen's Petition (Docket No. 94P-0427) on behalf of the American Women's Health Association, The American Public Health Association, and Planned Parenthood of New York City, asking the FDA to require two drug manufacturers to amend the labeling and package inserts of certain of their oral contraceptive products to include information regarding the use of these products as emergency contraception. On May 22, 1995, the FDA issued an "interim response" indicating that the request was "still under consideration" and that the agency required more time to "thoroughly evaluate[] the issues raised" in the petition and to finalize its decision. (Letter of Janet Woodcock, M.D., Director, CDER, dated May 22, 1995 (attached hereto as Exhibit A).)

40. On May 9, 1996, the FDA issued a letter denying the 1994 Citizen's Petition because "[a]lthough FDA agrees in principle that it has discretion to require that certain conditions of use be included in a product's labeling . . . we decline to exercise our discretion to require the relabeling of these products in the manner you suggest." (Letter of Janet Woodcock, M.D., Director, CDER, dated May 9, 1996 (attached hereto as Exhibit B).) However, the agency determined "that it would be appropriate to discuss the issue of the safety and effectiveness of oral contraceptives for postcoital emergency use with the Reproductive Health Drugs Advisory

Committee at its June 28, 1996 meeting. [The Center for Reproductive Law and Policy] will be invited to present [its] views at that meeting." *See id*.

41. On February 24, 1997, the Center for Reproductive Law and Policy received notice from FDA Deputy Commissioner Mary K. Pendergast that "today the Food and Drug Administration placed on public display a Federal Register notice concluding that certain combined oral contraceptives . . . are safe and effective for use as postcoital emergency contraception. The notice requests submission of new drug applications for this use . . . ." (Letter of Mary K. Pendergast, Deputy Commissioner, Senior Advisor to the Commissioner, FDA, dated February 24, 1997 (attached hereto as Exhibit C); *See also* Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception (Docket No. 96N-0492) (attached hereto as Exhibit D).)

42. FDA Federal Register Notice stated that "[t]his notice is intended to encourage manufacturers to make this additional contraceptive option available." Ex. D at 1. The agency agreed with the unanimous conclusion of the Advisory Committee, which met on June 28 1996 to consider this issue, that several regimens of oral contraception were safe and effective for postcoital emergency contraception. Id. at 3. The agency concluded that "[b]ecause of the publicly available safety and effectiveness data documenting the drugs' use, the safety and effectiveness requirements of § 314.50 may be met by citing the published literature listed in the references in section III. of this document." *Id.* at 8.

43. In 1999, the FDA approved Plan B as a prescription drug. Since that date, Plan B has been prescribed many thousands of times.

44. On February 14, 2001, a group of citizen organizations, including Plaintiff ARHP, filed a petition with FDA asking the agency to switch Plan B (and another drug, Preven, that has

since been removed from the market for reasons unrelated to safety and effectiveness) to OTC status. In violation of its own regulations, *see* ¶ 21 above, the FDA has failed as of the date of this Complaint to either approve, deny, or give a tentative response to the citizen's petition within 180 days of the filing of the petition, thus constructively denying the petition. After the 180 day period, the FDA gave a tentative response on September 6, 2001. Since that date the FDA has not communicated any further with the petitioners, and therefore the petition has been constructively denied.

C. Barr Laboratories Filed a Supplemental New Drug Application Seeking OTC Status for Plan B, Which Was Not Approved by the FDA Contrary to the Overwhelming Consensus of the Review Staff and Advisory Committee in Support of Approving the Application.

45. On April 16, 2003, Women's Capital Corporation, the former owner of Plan B, filed a supplemental new drug application (SNDA) asking the agency to approve Plan B for OTC sale. Plan B was subsequently sold to Barr Laboratories, which maintained the SNDA.

46. On December 16, 2003, FDA's Non-prescription Drugs Advisory Committee and Advisory Committee for Reproductive Health Drugs held a joint session to discuss possible OTC status for Plan B.

47. The advisory committees, comprised of 28 members, voted as follows:

> (1) Does the Actual Use Study (AUS) demonstrate that consumers used [Plan B] as recommended in the proposed labeling?
>
> Yes – 27 No – 1
>
> (2) Are the AUS data generalizable to the overall population of potential non-Rx users of Plan B?
>
> Yes – 27 No – 1
>
> (3) Based on the AUS and literature review, is there evidence that non-Rx availability of Plan B leads to substitution of emergency contraception for the regular use of other methods of contraception?

Yes – 0 No – 28

(4) Do the data demonstrate that Plan B is safe for use in the non-prescription setting?

Yes – 28 No – 0

48. Upon information and belief, all division chiefs within the Center for Drug Evaluation and Research (CDER) who reviewed the OTC switch application expressed the view to CDER based on scientific and medical data that the OTC switch should be approved.

49. By memorandum dated April 22, 2004 and signed electronically on April 28, 2004, John Jenkins, M.D., the Director of the FDA's Office of New Drugs, wrote a memorandum summarizing his "review, conclusions, and recommendations regarding" the OTC switch for Plan B (attached hereto as Ex. E) ("the Jenkins memorandum"). This memorandum states: "[The FDA] has not heretofore distinguished the safety and efficacy of Plan B and other forms of hormonal contraception among different ages of women of childbearing potential and I am not aware of any compelling scientific reason for such a distinction in this case." (Ex. E at 30898.) After a review of the record evidence supporting OTC use by women of all ages, the Jenkins memorandum accordingly concludes "that the available data clearly support a conclusion that Plan B meets the statutory and regulatory requirements for availability without a prescription for all age groups. Such a conclusion is consistent with how the Agency has made determinations for other OTC products, including other forms of contraception available without a prescription." (*Id.* at 30899.)

50. The Jenkins memorandum further states that "[o]ther senior officials within the Agency, including the former Commissioner (Dr. McClellan) and the Acting Center Director (Dr. Galson), have expressed concerns about the potential for unsafe, ineffective, or

inappropriate use of Plan B by adolescents if it were to be made available without a prescription. These concerns appear to have been based primarily on the limited number of adolescent women included in the sponsor's label comprehension and actual use studies." (*Id.* at 30897.)

51. Though Jenkins said that he "[is] sensitive to and respect[s] the concerns that some may have regarding non-prescription access to Plan B by adolescents," (*Id.* at 30898), he stated that "[p]roducts that are indicated for uses related to sexual activity in adolescents raise concerns for some people that go beyond a finding based on clinical trial data that the product is safe and effective for its intended use in adolescents. These concerns derive from individual views and attitudes about the morality of adolescent sexual behavior and also overlap with concerns about the role for parents and health care professionals in decisions about contraceptive use in adolescents." (*Id*. at 30898-99.) He concluded: "While OTC access to Plan B for adolescents may be controversial from a societal perspective, I cannot think of any age group where the benefit of preventing unplanned pregnancies and abortion is more important and more compelling." (*Id*. at 30899.)

52. On May 6, 2004, CDER Acting Director Steven Galson issued a "non-approvable" letter (attached hereto as Ex. F) ("the Galson letter") to Barr rejecting the OTC switch for Plan B. That action also constructively denied the citizen's petition.

53. The Galson letter asserts that Barr's SNDA could not be approved because Barr had "not provided adequate data to support a conclusion that Plan B can be used safely by young adolescent women for emergency contraception without the professional supervision of a practitioner licensed by law to administer the drug." (Ex. F at 10796.) This assertion is not supported by the agency record.

54. In the past ten years, Plan B is the only drug as to which the FDA has rejected advisory committee recommendations in favor of approving a drug for OTC status.

D. Barr Laboratories Filed an Amended Supplemental New Drug Application Seeking Age-Restricted OTC Status for Plan B, Which Also Was Not Approved, Contrary to the Overwhelming Consensus among Agency Reviewers in Favor of Approving the Application.

55. On July 22, 2004, Barr filed an amended SNDA seeking the OTC switch only for women aged 16 and higher. By statute, the defendant was required to act on Barr's amended SNDA within 180 days after it was filed. *See* 21 U.S.C. § 355(c)(1). On January 21, 2005, the FDA announced a delay of its decision on Barr's application beyond this statutory time limit.

56. The reviewing divisions and offices of FDA reviewed Barr's amended application and examined the concerns raised by senior officials to support their decision to issue a nonapprovable letter for OTC use of Plan B, but found that scientific evidence did not support these concerns. (Excerpts from Mem. of Donna J. Griebel, M.D., dated January 12, 2005 (attached hereto as Exhibit G) at 31033.)

57. In its review of Barr's amended SNDA, the FDA review staff again overwhelmingly agreed that despite Barr's application for limited OTC status for Plan B for women 16 and older, that the drug was suitable for -- and thus should be approved for -- full OTC access for women of all ages. (Review of Complete Response by Daniel Davis, M.D., dated January 12, 2005 (attached hereto as Exhibit H) at 1; Mem. Add. of Curtis J. Rosebraugh, M.D., dated January 12, 2005 (attached hereto as Exhibit I) at 2; Ex. G at 31031-33; Mem. of John Jenkins, M.D., dated January 14, 2005 (attached hereto as Exhibit J) at 31096-98; *see also* Mem. of Steven Galson, M.D., dated August 26, 2005 (attached hereto as Exhibit K) at 1.)

E. FDA Has Continued to Improperly Delay Approval of Plan B for Full OTC Status.

58. The Director and Deputy Director of the Division of OTC Drug Products and the Director of the Office of Drug Evaluation V stated that Plan B meets the criteria for unrestricted

OTC access, that data to the contrary was lacking, and that because of the strength of the data before the agency, it is "unclear what additional data could be provided on adolescent use that would be sufficient to lift the age restriction in the future." (Ex. I at 205.)

59. FDA documents indicate that prior to January 21, 2005, the review staff at FDA were actively reviewing Barr's application for split-label access to Plan B. FDA has disclosed approximately sixteen documents that were placed in the Plan B docket during the month of January 2005. After January 21, 2005 and prior to August 2005, only two additional documents were submitted.

60. Because the record indicates that Barr's application was not actively being reviewed after January of 2005, the seven month delay between the conclusion of the scientific review and any further agency action was unreasonable, and constitutes bad faith and improper agency action.

61. Subsequently, despite repeated assurances to the public, the United States Congress, and this Court that FDA action on the SNDA was imminent, the FDA has continued to fail to approve Plan B for OTC use.

62. On July 13, 2005, the Secretary of Health and Human Services Michael O. Leavitt assured United States Senator Michael Enzi that "the FDA will act on this application [regarding OTC status for Plan B] by September 1, 2005." (*See* Letter of M. O. Leavitt, dated July 13, 2005 (attached hereto as Exhibit L).) Counsel for the Government submitted the Leavitt letter to the Court and requested that the Court delay the judicial proceedings: "[g]iven the agency's commitment to take action on the pending Plan B application within the next 45 days, we respectfully submit that the most appropriate course of action would be to suspend the current

briefing schedule and stay this case until the FDA takes the anticipated action. . . ." (Def.'s Letter to the Court, dated July 25, 2005 (attached hereto as Exhibit M), at 2.)

63. Instead of the promised action, on August 26, 2005, FDA Commissioner Lester Crawford issued a letter to Joseph A. Carrado, stating that "the Agency is unable at this time to reach a decision on the approvability of the application because of unresolved issues that relate to your NDA . . . ." (*See* Letter of Lester Crawford, M.D., dated August 26, 2005 (attached hereto as Exhibit N) at 5.) The letter indicated that "[t]he Center for Drug Evaluation and Research (CDER) has completed its review of this application, as amended, and has concluded that the available scientific data are sufficient to support the safe use of Plan B as an OTC product, but only for women who are 17 years of age and older." (*Id.*) In this letter, FDA further stated that age-restricted OTC access would not be available for Plan B before the agency reaches a decision on "unresolved issues" regarding the feasibility of approving split-label access. (*Id.*)

64. Because FDA recognized that Plan B is suitable for approval for OTC use by women who are 17 years of age and older but not for younger women, and because FDA is not continuing to review the safety of Plan B for women under 17, the FDA has taken final agency action denying women under 17 OTC access to Plan B.

65. FDA sought public comment on "whether we should initiate a rulemaking to codify our interpretation of section 503(b) regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product." (Ex. N at 2.)

66. On August 31, 2005, Dr. Susan F. Wood, assistant FDA commissioner for women's health and director of the Office of Women's Health announced that she was resigning from her post in reaction to the agency's decision to continue to limit access to Plan B, stating: "I can no

longer serve as staff when scientific and clinical evidence, fully evaluated and recommended for approval by the professional staff here, has been overruled." *See* Marc Kaufman, *FDA Official Quits Over Delay on Plan B*, WASH. POST., Sept. 1, 2005, at A08 (attached hereto as exhibit O) at 1 (quoting Susan F. Wood).

67. On September 27, Dr. Wood appeared on the ABC television news program Nightline to discuss the failure of the agency to act in accordance with the scientific consensus in favor of approving Plan B for OTC use. *See* ABC News transcript, dated September 27, 2005 (attached hereto as Exhibit P) at 4-6 (citing "consensus . . . amongst the scientists and health professionals there that it should be approved," and the fact that "all of the scientific and professional staff who normally are the part of the decision-making at the agency . . . were cut out of the decision.").

68. Dr. Wood also stated that she was concerned about the lengthy delay that she anticipated as a result of the upcoming rule-making:

> Dr. Wood: . . . But I would argue that the decision to delay approval of this product over-the-counter is, in fact, a denial. And this is, again, in part why I resigned. Because by couching it as a delay and a non-decision, in fact denied women of all ages, not just teens but women of all ages access to timely use of this product.
>
> Ted Koppel: (Off Camera) If you had thought that it was a brief delay, in other words, if you thought it was only going to be a delay of a couple of months, you wouldn't have resigned.
>
> Dr. Wood: Probably not.
>
> Ted Koppel: (Off Camera) So, you obviously think that what we're talking about here is not really a delay but a way of shelving it and not dealing with the issue.
>
> Dr. Wood: Right. The mechanism is a rather bureaucratic one to potentially open it up to rulemaking. Which, to make a long story short, means opening up to a process that usually takes many months to years, if in fact that's the way they go.

(*See* Ex. P at 6-7.)

F. The Government Accountability Office Investigated FDA's May 2004 Decision Not to Approve Plan B for Full OTC Status and Found that the FDA's Review Process Regarding Plan B Was "Unusual."

69. The Government Accountability Office commenced an investigation for the United States Congress into why the FDA rejected the OTC switch on May 6, 2004.

70. On November 14, 2005, the Government Accountability Office issued a report to members of Congress examining the FDA's May 6, 2004 issuance of a "non-approvable" letter with regard to Barr Laboratory's SNDA request that Plan B be made available over-the-counter. (attached hereto as Exhibit Q, also available at http://www.gao.gov/new.items/d06109.pdf).

71. The report, titled "Food and Drug Administration Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual," found that FDA's review process was "unusual" in four aspects:

> First, the Directors of the Offices of Drug Evaluation III and V, who would normally have been responsible for signing the Plan B action letter, disagreed with the decision and did not sign the not-approvable letter for Plan B. The Director of the Office of New Drugs also disagreed and did not sign the letter. Second, FDA's high-level management was more involved in the review of Plan B than in those of other OTC switch applications. … Third, … there are conflicting accounts of whether the decision to not approve the application was made before the reviews were completed. Fourth, the rationale for the Acting Director of CDER's decision was novel and did not follow FDA's traditional practices. Specifically, the Acting Director was concerned about the potential impact that the OTC marketing of Plan B would have on the propensity for younger adolescents to engage in unsafe sexual behaviors because of their lack of cognitive maturity compared to older adolescents. He also stated that it was invalid to extrapolate data from older to younger adolescents in this case. FDA review officials noted that the agency has not considered behavioral implications due to differences in cognitive development in prior OTC switch decisions and that the agency has considered it scientifically appropriate to extrapolate data from older to younger adolescents.

(Ex. Q at 5.)

72. In summary, the GAO found that the decision-making process was "not typical," was unlike all of the 67 other OTC switch applications filed between 1994 and 2004, and that the

Plan B OTC switch application was the only one during that 10 year time period that "was not approved after the joint committee voted to recommend approval of the application." *Id.* The GAO Report concludes that the FDA's decision-making process was unusual and that high-level officials were reported to be involved in the decision-making process.

73. Former FDA Commissioner Mark McClellan refused to be interviewed by the GAO investigators and refused to answer written questions submitted by them regarding the decision to issue a non-approvable letter to Barr in May 2004.

74. Former FDA Commissioner Mark McClellan improperly deleted electronic correspondence related to the OTC application for Plan B. See (Letter of United States Congressman Henry Waxman, dated November 15, 2005 (attached hereto as Exhibit R).)

75. Former FDA Commissioner Lester Crawford also declined to be interviewed by the GAO in conjunction with their report.

G. Government Documents Confirm the Findings of the GAO Report that Upper Level Management Were Unusually Active in the Decision-Making Process Regarding the OTC Switch Application for Plan B, and that Upper Level Management Overrode the Recommendations of the Review Staff.

76. The administrative record compiled by the agency confirms that as early as January 15, 2004, upper level management at FDA had decided that the OTC switch for Plan B would not be approved, and that this decision was made before the scientific review of the OTC switch application was complete.

77. The administrative record compiled by the agency confirms that the Office of the Commissioner was involved in the agency's review of the OTC switch application for Plan B since at least December 10, 2003, and that the concerns about adolescent use of Plan B expressed by Dr. Galson in his May 2004 non-approvable letter, as well as the concerns about adolescent

use of Plan B expressed by Dr. Galson in his August 26, 2005, memorandum, echo and reflect the concerns of the Office of the Commissioner expressed in January of 2004.

78. Documents show that both the Commissioner of the FDA and the Deputy Commissioner of Operations played an unusually active role in the decision to issue a non-approvable letter, as well as in subsequent agency action on Plan B. The Directors of the Offices of Drug Evaluation III and V told GAO investigators that they were asked by high level management to draft and sign a non-approvable letter for Plan B, but that they declined to do so because they did not agree with that action. The Director of the Office of New Drugs was then asked to review the Plan B application. Involving the Office of New Drugs in issuing such a letter is very rare and, according to FDA policy and procedure manuals is limited to situations where there is disagreement between the two reviewing offices. (Ex. Q at 20). The Director of the Office of New Drugs also declined to sign a non-approvable letter based on his disagreement with the decision. *Id.*

79. The fact that upper-level management at FDA removed the decision of whether to approve Plan B's OTC application from the hands of the professional review staff, that upper-level management dictated the outcome of the review process, and that upper-level management deviated from the standard practices and policies set forth in their own manuals and handbooks, suggests that the FDA impermissibly held the Plan B OTC switch application to a higher standard than other drugs, and that doing so constitutes bad faith and improper agency action.

80. The FDA's Deputy Director of the Office of Drug Evaluation V stated in a memorandum that the issues raised by FDA political appointees concerning adolescents' access to Plan B "spuriously raise the review standard for approval of this product and indeed any contraceptive product," and are not supported by the data nor the medical literature.

81. In the past ten years, except in the case of Plan B and certain nicotine-related drugs, FDA has never requested additional data regarding adolescents to be submitted by manufacturers seeking OTC switches.

82. The non-approvable letter in May 2004 and the August 26, 2005 decision to further withhold approval of Plan B for OTC use were opposed by the scientific review staff that would normally be responsible for making decisions approving drugs for OTC use. CDER reviewers in the Divisions of Reproductive and Urologic Drug Products and the Division of Over-the-Counter Drug Products, the Deputy Directors of the Offices of Drug Evaluation III and V, and the Director of the Office of New drugs all recommended that Plan B should be switched OTC for women of all ages.

H. FDA's Failure to Approve Plan B for Full OTC Use Constitutes Bad Faith and Improper Agency Action, and Treats Plan B Differently than Other Drugs Without Any Medical or Scientific Basis for that Differential Treatment.

83. The FDA applied a different and higher standard to Plan B's OTC switch than it has applied to OTC switches of other drugs.

84. There is no medical or scientific basis for the FDA's application of a different and higher standard to Plan B's OTC switch.

85. The FDA's failure to approve Plan B for OTC use is based in part on outmoded stereotypes of women and girls.

86. The FDA's application of a different and higher standard to Plan B's OTC switch was the result of factors that fall outside the FDA's statutory mandate, including impermissible ideological factors.

87. The FDA's rejection of the OTC switch for women of all ages and the FDA's constructive rejection of the citizen's petition for the OTC switch are not supported by medical or scientific evidence and are not supported by the agency record.

88. Where upper level agency management made decisions regarding the status of the Plan B application before the scientific review process has been completed, such premature decision-making constitutes bad faith and improper action by an agency dedicated to promoting and protecting public health.

89. The former FDA Commissioner Mark McClellan's destruction of email correspondence and refusal to cooperate with the GAO's investigation constitute bad faith and improper agency action.

90. The fact that the Secretary of Health and Human Services (HHS) submitted a letter to the Senate assuring Senators that FDA would act on the OTC application for Plan B by September 1, 2005, but that the only action subsequently taken by the agency was to invite public comment on a proposed rulemaking proceeding, constitutes bad faith and improper agency action.

91. Each of the plaintiffs is aggrieved on a continuing and ongoing basis by the FDA's rejection of the OTC switch for women of all ages and the FDA's constructive rejection of the citizen's petition for the OTC switch.

92. Each of the plaintiffs is injured on a continuing and ongoing basis by the FDA's rejection of the OTC switch for women of all ages and the FDA's constructive rejection of the citizen's petition for the OTC switch, and the FDA's rejection is the cause of that injury.

93. The relief sought in this complaint will redress the injury suffered by each of the plaintiffs that is caused by the FDA's constructive rejection of the citizen's petition for the OTC switch for women of all ages.

V. Causes of Action

FIRST CAUSE OF ACTION: ARBITRARY AND CAPRICIOUS

94. Plaintiffs hereby incorporate by reference ¶¶ 1-93 above.

95. FDA's denial of the OTC switch for persons of all ages is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, in violation of 5 U.S.C. § 706(2)(a) (2005) in that the FDA required evidence of safety and efficacy beyond that required for approval of any other drugs and was improperly motivated by factors other than medicine and science, and because the evidence of safety and efficacy before the FDA demonstrates that it should be made available without prescription.

SECOND CAUSE OF ACTION: EXCEEDS STATUTORY AUTHORITY

96. Plaintiffs hereby incorporate by reference ¶¶ 1-95 above.

97. FDA's denial of the OTC switch for persons of all ages exceeds its statutory authority in violation of 5 U.S.C. § 706(2)(c) in that it was improperly motivated by factors other than medicine and science.

THIRD CAUSE OF ACTION: RIGHT TO PRIVACY

98. Plaintiffs hereby incorporate by reference ¶¶ 1-97 above.

99. FDA's denial of the OTC switch for persons of all ages violates the Fifth Amendment to the United States Constitution and 5 U.S.C. § 706(2)(b) in that it infringes the right to privacy of women who need EC without serving any compelling, significant, or legitimate governmental interest.

FOURTH CAUSE OF ACTION: EQUAL PROTECTION

100. Plaintiffs hereby incorporate by reference ¶¶ 1-99 above.

101. FDA's denial of the OTC switch for persons of all ages violates the Fifth Amendment to the United States Constitution and 5 U.S.C. § 706(2)(b) in that it discriminates on the basis of sex without serving any compelling, significant, or legitimate governmental interest.

102. FDA's denial of the OTC switch for persons of all ages violates the Fifth Amendment to the United States Constitution and 5 U.S.C. § 706(2)(b) in that it discriminates on the basis of the exercise of the fundamental right to privacy without serving any compelling, significant, or legitimate governmental interest.

FIFTH CAUSE OF ACTION: ACTION UNLAWFULLY WITHHELD OR UNREASONABLY DELAYED

103. Plaintiffs hereby incorporate by reference ¶¶ 1-102 above.

104. FDA's failure to approve the OTC switch for Plan B constitutes an action "unlawfully withheld or unreasonably delayed" in violation of 5 U.S.C. § 706(1).

VI. Prayer for Relief

WHEREFORE, Plaintiffs ask this Court:

A. To issue an injunction ordering Defendant to approve the OTC switch for persons of all ages;

B. To enter judgment declaring the denial of OTC availability to persons of all ages in violation of the United States Constitution and 5 U.S.C. § 706; and

C. In the event the Court finds that the Agency has not taken final action, to order the agency to issue a final decision on the OTC status of Plan B, and to enter a declaratory judgment that the FDA has unlawfully withheld or unreasonably delayed issuing such a decision, in violation of the Constitution of the United States and the Agency's statutory mandate.

D. To grant such other and further relief as this Court should find just and proper, including attorneys' fees and costs.

Dated: January 27, 2006.

Respectfully submitted,

/s Simon Heller
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CERTIFICATE OF SERVICE

I, Simon Heller, hereby certify that on January 27, 2006, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which sent notification via electronic mail to F. Frank Amanat.

Dated: January 27, 2006

Respectfully submitted,

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